

REMARKS

Reconsideration of the present application is requested in view of the above amendments and following remarks.

Discussion of the Amendments

Claim 59 has been amended to more particularly define applicant's invention as that of an immunoassay for human LIPG in a human tissue sample. Support for this amendment is found in the application at now cancelled Claim 104, which mirrors originally filed Claim 61. Claims 104 and 105 has been cancelled without prejudice. No new matter has been added. The presently-pending elected claims are Claims 59 and 103.

A "Description of the Sequences" section has been added to the descriptive portion of the application. Support for this is found in the "Brief Description of the Drawings" section of the application, the Sequence Listing as filed, and at pages 104, 105, and 107 of the application as filed.

Discussion of the Examiner's Rejection of Claims 59 and 103
Under the Enablement Requirement of Section 112, First Paragraph

The Examiner rejected Claims 59 and 103 because, according to the Examiner, applicants have not enabled such methods for use when the LIPG and the tissue sample are not from a human source. This has been overcome by the above amendment to the claims in which the LIPG and the tissue sample are defined as being from a human source.

The Examiner rejected Claims 59 and 103 also because, according to the Examiner, it has not been shown that LIPG levels are predictive of the levels of HDL and apolipoprotein AI. This rejection has been rendered moot by the above amendment to Claim 59 from which Claim 103 depends. The claims now define a method for conducting an immunoassay for human LIPG in a human tissue sample. The method no longer claims to be one for diagnosing a predisposition to low HDL cholesterol and apolipoprotein AI levels.

Discussion of the Examiner's Rejection of Claims 59 and 103
Under the Written Description Requirement of Section 112, First Paragraph

The Examiner rejected Claims 59 and 103 because, according to the Examiner, applicants have not described such methods for use when the LIPG polypeptide and the tissue sample are not from a human source. This has been overcome by the above amendment to the claims in which the LIPG polypeptide and the tissue sample are defined as being from a human source.

Discussion of the Examiner's Rejection of
Claims 59 and 103 Under Section 112, Second Paragraph

In the Action, the Examiner objected to the claims because she felt the term "LIPG polypeptide" to be unclear. She recommended that the claims be amended to refer instead to "endothelial lipase (LIPG) polypeptide". This has been done with the above amendments.

The Examiner objected also to the claims because, according to the Examiner, it is not clear which specific polypeptide is being referred to by the

phrase "LIPG polypeptide". According to the Examiner, this is not remedied by the descriptive portion of the application. Applicants note, however, that "LIPG polypeptide" is clearly defined on page 30 of the application as being a lipase enzyme encoded by the LIPG gene. Thus it should be abundantly clear where the boundaries of the definition "LIPG polypeptide" are since any lipase enzyme encoded by the LIPG gene is an LIPG polypeptide and those which are not encoded by the LIPG gene are not LIPG polypeptides. The Examiner went on to state that the description of the Figures describes various LIPG polypeptides but the application does not describe the relationship between them. This is not true since only two LIPG polypeptides are described in the description of the Figures section: LLGXL (SEQ ID NO. 8); and LLGN (SEQ ID NO. 6). The relationship between these two LIPG polypeptides is that they are both encoded by the LIPG gene. This is described in the application at page 25 and 26. While LLGXL and LLGN are different polypeptides, this does not detract from the fact that they are both encoded by the LIPG gene. In any event, the differences between the two are clearly described in the application at page 82 and 83. The Examiner claims that it is not clear which LIPG polypeptide is being referred to in the claims. Applicants note, however, that the term "LIPG polypeptide" refers to any polypeptide encoded by the LIPG gene (see page 30, lines 4 to 6). Thus the polypeptide may be LLGXL, LLGN, or any other polypeptide encoded by the LIPG gene. With respect to Claim 59, it should be understood that "LIPG" refers to any polypeptide encoded by the LIPG gene (as evidenced by the above definition) and, therefore, the method refers to measuring the level of any such polypeptide.

The remainder of the Examiner's rejection of the claims under Section 112, second paragraph, have been rendered moot by the above amendment.

Submission of Formal Drawings

In response to the Patent Office's request for substitute drawings, enclosed herewith are: (A) thirty (30) sheets of substitute drawings (Figures 1 to 28); and (B) a copy of the relevant Notice of Draftperson's Patent Drawing Review.

Discussion of the Examiner's Statement Regarding Compliance with Sequence Rules

In the Action the Examiner objected because the polynucleotide sequence depicted in Figure 6 is not defined either in the Figure or in the description of the Figure. The polynucleotide sequence is the coding portion of SEQ ID NO. 7. The description of the drawings section of the application has been amended to identify this sequence. As this sequence is already in the Sequence Listing, there is no need to provide a substitute copy of the Sequence Listing.

Discussion of the Examiner's Objection to the Descriptive Portion of the Application

The Examiner objected to amendments made in the November 6, 2002 Action in which five paragraphs were inserted at page 25, between lines 7 and 8. According to the Examiner, such material is new matter. Applicants, however, disagree respectfully. Support for these paragraphs is found in the application as filed originally at page 25, line 1, to page 27, line 29; page 29, line 23, to page 30, line 3; and page 35, line 24, to page 36, line 11, and in the Sequence Listing as filed.

In addition to the above, the Examiner asserted that SEQ ID NOS: 5 and 9 are not described in the descriptive portion of the application. This is not correct. SEQ ID NO: 5 is described in the application at page 83, lines 1 to 4. SEQ ID NO: 9 is described in the application at page 83, line 8 to 10.

The Examiner's objection to the application for not having up-to-date continuity data has been addressed by the above amendment.

The Examiner objects to the application for not having a clear description of the sequences in the Sequence Listing. This has been remedied by the above amendment in which such a description has been added. The Examiner, however, noted that the relation of LLGN (SEQ ID NO. 6) to LLGXL (SEQ ID NO. 8) is unclear and her belief that LLGN is a truncated version of LLGXL. This is not true. These are two different polypeptides encoded by two different mRNA products, as exhibited by their different corresponding cDNAs (SEQ ID NOS. 5 and 7, respectively), both of which are mRNA products of the LIPG gene. SEQ ID NO. 10 is the amino sequence which is common to both SEQ ID NOS. 6 and 8 and SEQ ID NO. 9 is the nucleic acid sequence encoding it.

The Examiner objected to the "Brief Description of the Drawings" section for inaccurate descriptions of Figures 2, 3, and 13. This has been remedied by correction of Figures 2 and 3 and by the above amendment of the description for Figure 13.

Discussion of the Examiner's Objection to the Abstract

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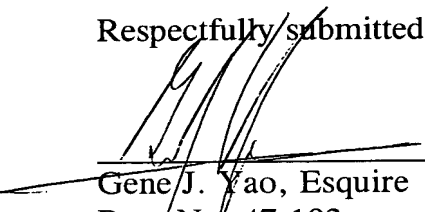
The Examiner's objection to the abstract has been addressed by the above amendment.

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An early and favorable Action is requested.

Respectfully submitted,



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Amendments to the Drawings

Attached to this Reply are replacement sheets for Figures 2 and 3. The Figures are being amended to be consistent with the description of the figures on pages 20 and 21 of the application. In the description, the figures are identified as containing the amino acid sequence coded for by the nucleic acid sequences depicted in the figures. The figures, prior to amendment, however contained additional amino acid sequences 5' and 3' of the region actually encoded. These additional sequences are not encoded by the nucleic acid and, therefore, do not belong in the figures. With the present replacement sheets, these sequences have been removed.



REPLACEMENT SHEET

2 / 30

GAATTCGGCTTGATCAATCGCTTCAAAAAGGGGATCTGTCTGAGCTGCCGCAAGAACCGTTGTAATAG

CATTCGCTACAATGCCAAGAAAATGAGGAACAAGAGGAACAGCAAAAATCTACCTAAAAACCCGGGCAG

— Coding region —

F K K G I C L S C R K N R C N S
GCCTTTCAGAGGTAACCTTCAGTCCCTGGAGTGTCCCTGAGGAAGGCCCTTAATACCTCCTTCTTAAT

— Coding region —

I G Y N A K K M R N K R N S K M Y L K T R A
ACCATGCTCAGAGCAGGGCACATCCTAGCCAGGAGAAGTGGCCAGCACAAATCCAATCAAAATCGTTG

— Coding region —

P F R G N L Q S L E C P
TCAGATTACACTGTGCATGTCTCCTAGGAAGGGAATCTTTACAAATATAACAGTGTGGACCCCTCAAAA

AAAAAAAAAGCCGAATTC

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FIG. 2



REPLACEMENT SHEET

3 / 30

GAATTGGGCTTCTACTACTAGGCCACGGTCGCCTAGTACGGGGGGGGGGGGGTGACGGAG

TCCTTGCCCTCCCGGGGCTCAGGACGAGGGCAGATCTCGTTCTGGGCAAGCCGTTGACACTCGCTCC

CCCCGGCTCCGTCGCCCAAGTTTTCATTTTCCACCTTCTCTGCCTCCAGTCCCCCAGCCCCCTGGCCG

AGAGAGGGTCTTACGGCCGGGATTGCTGGAAACACCAAGAGGTGGTGTGTTTTTAAACTTCT

GAGGGGTGTGGCGGGCAGGATGAGCAACTCCGTTCTCTGCTGTGTTCTGGAGCCTCTGCTATTG

CTTTGCTGGGGAGCCCCGTACCTTTTGGTCCAGAGGGACGGCTGGAAGATAAGTCCACAAACCCA

———— Coding region: 5' RACE extension ————

M S N S V P L L C F W S L C Y C
AGACTGAGGTCAAACCATCTGTGAGGTTTAACTCCGCACCTCCAAGGACCCAGAGCATGAAGGATGC

———— Coding region: 5' RACE extension ————

F A A G S P V P F G P E G R L E D K L H K P
TACCTCTCCGTCGGCCACAGCCAGCCCTTAGAAGACTGCAGTTTCAACATGACAGCTAAACCTTTT

———— Coding region: 5' RACE extension ————

Q T E V K P S V R F N L R T S K D P E H E G C
CGGATGGACGATGAGCGGTATCTTTGAAAACCTGGCTGCACAAACTCGTGTGAGCCCTGCACACAAGAG

———— Coding region: 5' RACE extension ————

Y L S V G H S Q P L E D C S F N M T A K T
AGAAAGACGCCAATGTAGTTGTGTTGACTGGCTCCCCCTGGCCACCAGCTTTACACGGATGGGTC

FIG. 3A



REPLACEMENT SHEET

4 / 30

Coding region:5'RACE extension
G W T M S G I F E N W L H K L V S A L H T R
AGGTTGGTGACACAGCATTCAGGATGCTCGACTGGCTGCAGGAGAAGGACGATTTTCTCTCTCGG

Coding region:5'RACE extension
E K D A N V V V D W L P L A H Q L Y T D A V
GAATGTCCACTTGATCGGCTACAGCCTCGGAGCGCACGTGGCCGCTATGCAGGCAACTTCGTGAAAG

Coding region:5'RACE extension
R V V G H S I A R M L D W L Q E K D D F S L G
GCCGAATCACAGGTTGGATCCTGCCGGGCCCATGTTGAAGGGCCGACATCCACAAGAGGCTCTCT

Coding region:5'RACE extension
N V H L I G Y S L G A H V A G Y A G N F V K
CCGGACGATGCAGATTTGTGGATGTCCTCCACACCTACAGCGTTCCTTCGGCTTGAGCATTTGGTAT

Coding region:5'RACE extension
G R I T G L D P A G P M F E G A D I H K R L S
TGTGGGCCACATTCACCCCAATGGGGTGACTTCCAGCCAGGCTGTGGACTCAACGATGTCT

Coding region:5'RACE extension
P D D A D F V D V L H T Y T R S F G L S I G I
TGGGATCAATTGCATATGGAACAATCACAGAGGTGGTAAATGTGAGCATGAGCGAGCCGTCACCTC

Coding region:5'RACE extension
V G H I D I Y P N G G D F Q P G C G L N D V
TCTCTGGTGAATCAGGACAAGCCGAGTTTTCCTTCAGTGCACTGACTCCAATCGCTTCAAAAAGGG

Coding region:5'RACE extension
L G S I A Y G T I T E V V K C E H E R A V H L
GATCTGTGAGCTGCCGCAAGAACCGTTGTAATAGCATTTGGCTACAATGCCAAGAAAATGAGGAACA

FIG. 3B



REPLACEMENT SHEET

5 / 30

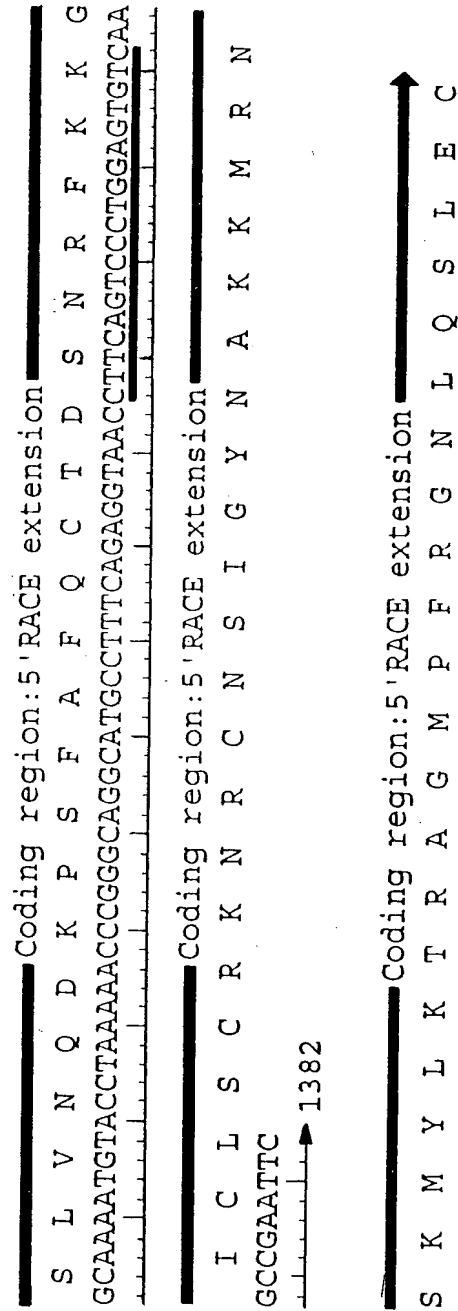


FIG. 3C